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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,423	12/18/2001	Ronald N. Zuckermann	16141.003	6469

7590 03/10/2006

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EXAMINER	
WESSENDORF, TERESA D	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,423	ZUCKERMANN ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-17,21 and 24-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-17,21 and 24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/12/2005 has been entered.

Status of Claims

Claims 13-17, 21 and 24-29 are pending and under examination in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-17, 21, 24-29, as amended, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the

written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy a written description requirement for a claimed genus a sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

The specification fails to provide an adequate description of the different-sequence peptoids that include variations selected from different N-side chains, different terminal lipid moieties, and different distributions of neutral and cationic N-side chains. The specification at page 11, line 20 up to page 12, line 5 provides a list of the cationic N-side chains that does not preclude those that are not listed therein. Likewise, the different lipid moieties are listed and at least two neutral

N-side chains. Other than this list, the disclosure does not describe in detail the means or method of the various combinations to arrive at the claimed peptoid library. There is no indication in the disclosure that the peptoid combination would function efficiently as a delivery agent for oligonucleotides. The detailed description, provided in the specification Examples recited for a peptoid oligmer modified from the previous methods described in the published work of Zuckermman et al. It is not apparent from this description the modifications i.e., the kind of N-side chains or lipid moiety and the location of said modifications along the peptoid chain. The Examples describe only a peptoid-cholesterol conjugate. There is no correlation as to this single species to the huge scope of the different undefined variations of lipid moieties, cationic and neutral N-side chains. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure indicates that the applicants have invented species sufficient to constitute the gen[us]. Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004). In biotechnological art, particularly in the delivery of compounds, e.g., oligonucleotide to cells, one cannot predict whether the compound is safely and efficiently transfected to the intended

cells by the carrier. One skilled in the art is not provided enough guidance or direction as to the correlation of the single species to the numerous different undefined structure of the generic claim. {Incorporating the structure of claim 24 to claim 1 would obviate this rejection.]

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 16 is indefinite as the recited "the particles in said compartments" lack antecedent basis of support from the base claim.

B. Claim 24 is confusing in the recitation of the clause "wherein at least one group Rb is not hydrogen". Is Rb made up of several groups?

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-17, 21 and 24-29 are rejected on the ground of nonstatutory double patenting over claims 1-2 of U. S. Patent No. 6677445 ('445 Patent). since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject

matter, as follows: a peptoid-oligonucleotide mixture useful for a method of transfecting cell. (See col. 5, line 65 up to col. 7, line 45 of the '445 Patent).

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 13 and 21, as amended, are rejected under 35 U.S.C. 102(e) as being anticipated by Liotta (USP 6,153,596).

The claimed method of identifying peptoids in a library of different sequence peptoids comprising of the recited steps (i)-(iv) is fully met by the method of Liotta. Liotta discloses the same method of transfecting cell with an oligonucleotide by administering peptoids as taught at col. 7, line 54 up to col. 18, line 11, specifically col.14, lines 40-56.

Claim Rejections - 35 USC § 103

Claims 13-17, 21 and 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable Liotta (USP 6,153,596) in view of Murphy (PNAS).

Liotta is discussed above. Liotta does not disclose a peptoide of general formula I as recited in claim 24, for example. However, Murphy discloses at page 1518, RESULTS and DISCUSSION section up to page 1521, col. 1 that peptoid with lipid derivatized at the N-end results in a highly efficient transfection agent. The ability to derivatize a defined site in the peptoid side chain will allow for the controlled synthesis

of delivery vehicles modified with targeting ligands. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the peptoid of Murphy in the method of Liotta. The advantages disclosed by Murphy, above would provide the motivation to do such substitution.

Claim 14 is obvious in view of the disclosure of Murphy as to the use robotic synthesizer, page 1517, col. 2.

Claim 26 is obvious in view of the teachings of Liotta as to the advantage in the use of sterol as a side group e.g., sterol tethered in the peptoid chain. See col. 12, lines 20-30 and col. 16, lines 29-39.

Response to Arguments

Applicants acknowledged that Liotta et al describes the use of polycationic polymers, which include peptoids for transfection of nucleic acids including oligonucleotide. But argue that Liotta et al teaches that sequence per se is not an important factor in electrostatic binding between nucleic acids and cationic peptides or peptoids. Rather, Liotta teaches that, in cationic oligomers, such as peptoids, length of oligomer and spacing of cationic side groups are critical factors in determining their effectiveness in oligonucleotide transfection.

It is further argued that Liotta teaches that length of oligomer and spacing of cationic side groups, not sequence per se are the primary factors in determining the effectiveness of cationic oligomers in the transfection.

In response, applicants' arguments as to the different factors of the peptoids are irrelevant to the prima facie finding of obviousness. Liotta teaches transfection of oligonucleotide by the peptoids (cationic polymers). Simply because Liotta provides the different factors/guidelines as to the kind of peptoides do not detract from the finding of obviousness. Rather, this would provide direction to one having ordinary skill in the art. The claims do not preclude such factors or the sequence of Liotta i.e., claim 13.

Applicants argue that there is no suggestion in Liotta et al that varying the nature or sequence of these groups from the general pattern (i.e., varying the sequence of the peptoids) would be desirable or would increase transfection efficiency. There is no motivation provided in Liotta, therefore, to screen a "library of different- sequence peptoids" for oligonucleotide transfection, as claimed by the applicants. As noted above, Murphy et al. do not address transfection of oligonucleotides at all.

In reply, Liotta teaches a library of different-sequence peptoids i.e., polycations or polycation and Ala. Murphy also teaches a library of different-sequence peptoids. The combined teaching of the prior art at the time the invention was made is prima facie obvious to one having ordinary skill in the art. The test for combining references is not what the individual references themselves suggest but rather what the combination of the disclosures taken as a whole would suggest to one of ordinary skill in the art. In re McLaughlin, 170 USPQ 209 CCPA 1971. The issue of patentability must be approached in terms of what would have been obvious to one of ordinary skill in the art ***at the time the invention was made*** in view of the sum of all the relevant teachings in the art, not in view of the first one and then another of the isolated teachings in the art. In re Kuderna, 165 USPQ 575 CCPA 1970.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
March 3, 2006